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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,549	03/30/2004	David Milton Hadley	330498003US	9985

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EXAMINER

AGUEL, FERNANDO

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/816,549

Applicant(s)

HADLEY ET AL.

Examiner

Fernando Aguel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,10 and 16 is/are rejected.
- 7) ☒ Claim(s) 3-5,8,9,11-15,17 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/12/04 & 8/20/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 8/12/04 and 8/20/04 are noted. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 2 recites the limitation "wherein specific phases" but there is insufficient antecedent basis for this limitation in the claim since the specific phases were not introduced prior to this reference.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al (5437285) in view of Lander (5827195). Verrier et al disclose a method by which alternan waveform is calculated by subtracting successive ECG waveforms (column 16, lines 57 – 62) and another method by which an alternan waveform is obtained by performing a least squares estimate of the amplitudes of the alternans (column 17, lines 26 – 33). Verrier et al disclose that the analysis may be done in real-time or processed at a later time (column 14, lines 65 – 68). Verrier et al do not teach a method for compensating for disturbances or ectopic beats in the preliminary alternan waveform. Lander teaches a method for compensating for ectopic beats by excluding these beats (column 14, lines 6 – 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al by compensating for ectopic beats in the alternan waveform in order to more accurately convey the information relating to the risk of cardiac instability. Furthermore, since it is well known in the art that alternan waveform features are indicative of cardiac instability, it would have been obvious to one of ordinary skill in the art at the time the invention was made to decompose the final alternan waveform into amplitude and frequency features to provide information relating to changes in cardiac potentials of the subject. It would also have been obvious to one of ordinary skill in the art at the time the invention

was made to perform the analysis at a later time using a computer that can be easily programmed to perform the analysis.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al (5437285) and Lander (5827195) as applied to claim 1 above, and further in view of Nearing et al (US 2005/0010122). Verrier et al and Lander disclose the invention substantially as claimed but do not disclose using the amplitude of scaling factors in assessing cardiac instability. Nearing et al teach multiplying the waveform by a scaling factor to compare the normalized waveform to a predetermined value (paragraph 60, lines 1 – 9) to assess how a disease changes ECG amplitude (paragraph 62), which is an indicator of cardiac risk. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al and Lander by including the amplitudes of scaling factors in the assessment of cardiac instability as taught by Nearing et al in order to more easily compare a scaled/normalized waveform to the predetermined values.

8. Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al (5437285) and Lander (5827195) as applied to claim 1 above, and further in view of Arnold et al (5713367). Verrier et al and Lander disclose the invention substantially as claimed but do not disclose that the preliminary alternan waveforms associated with a selected time period are used to assess the risk of cardiac instability. Arnold et al teach looking at particular temporal pattern of cycle-to-cycle variability in physiologic waveforms (column 41, lines 11 –19) to determine the patient's risk of cardiac instability (column 41, lines 33 – 35). It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al and Lander by including evaluating preliminary alternan waveforms associated with a selected time period to assess cardiac instability as taught by Arnold et al in order to more easily and more quickly determine the risk of cardiac instability.

Allowable Subject Matter

9. Claims 3 – 5, 8, 9, 11 – 15, 17, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Arnold et al (5570696)
- b. Nearing et al (6169919)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fernando Aguel whose telephone number is 571-272-8687. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FA

Fernando Aguel
9/15/05

George Manuel